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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/068,812
Filing Date: February 04, 2002
Appellant(s): GREFF, RICHARD J.

GLENN M. SEAGER
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 07, 2010 appealing from the Office action mailed June 08, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 22-38, 42, 43 and 45-47 are pending.

Claims 34-38, 43 and 45-47 are withdrawn from consideration as being directed to non-elected invention.

Claims 22-33 and 42 are appealed.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 22-33 and 42 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

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US 4,292,972	Pawelchak et al.	10-1981
JP 02-182259	Yasushi et al.	07-1990
EP 568334	Song et al.	11-1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

- A.** Claims 22-25, 27-30, 32, 33, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Pawelchak et al. (US 4,292,972).

Current claim 22 is directed to a composition comprising: a cross-linked gelatin sponge and a wetting agent that is soluble in a non-aqueous solvent wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent.

Pawelchak disclosed sponge product comprising hemostatic bioabsorbable cross-linked gelatin foam (abstract; col.3, lines 18-22, 30-33, 44-46; the claims). The product comprises from about 10% surface tension modifier including polyoxyethylene derivatives of sorbitan fatty acid esters, such as Tween 60 (col.4, lines 47-56). The surface active agents disclosed by the reference are identical to those instantly claimed as wetting agents, and inherently are soluble in non-aqueous solvents. Pawelchak further disclosed up to 30% glycerin (col.5, lines 35-40; examples 6 and 18), which also

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reads on wetting agent and inherently are soluble in non-aqueous solvents. The reference disclosed method of making the foam by forming dispersion containing aerated foamed gelatin, which reads on preformed gelatin, and adding the surfactant and/or glycerin to the dispersion, followed by drying of the dispersion and forming a sponge product (col.4, lines 40-47, 60-68; col.5, lines 1-2). Adding the surfactant and/or glycerin to the dispersion containing foamed aerated gelatin meet the limitation of coating the gelatin with the wetting agent as instantly claimed by claim 22 because applicants coated the gelatin foam by soaking the foam in dispersion containing the wetting agent. The product is sterilized and packaged (col.5, lines 3-8). Although reduction of the hydration time is directed to the intended use of the product, however, the product disclosed by the reference that comprises cross-linked gelatin and the same wetting agent inherently decreases the hydration time of the cross-linked gelatin that claimed in claim 22. The foamed sponge further comprises antimicrobial agent and hemostatic agent such as thrombin (col.5, lines 29-35). The solubility and absorbability of the foam product can be reduced by reducing cross-linking (col.3, lines 36-39).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

- B.** Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak et al. in view of JP 02-182259 ('259).

The teachings of Pawelchak are discussed above.

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Although Pawelchak teaches anionic surfactants, however, does not explicitly teach alkyl (C_6 - C_{20}) sulfate salts, aryl (C_6 - C_{10}) sulfate salts, and alkaryl (C_7 - C_{24}) sulfate salts as claimed by claim 26.

JP '259 teaches composition comprising cross linked gelatin impregnated with surfactant (abstract). The surfactants include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph).

Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to provide hemostatic composition comprising cross linked gelatin sponge and anionic surfactant (wetting agent) as taught by Pawelchak, and replace the anionic surfactant with sodium lauric sulfuric acid taught by JP '259. One would have been motivated to do so because JP '259 teaches the equivalency between sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester as anionic surfactant added to the hemostatic gelatin sponge product. One would reasonably expected formulating hemostatic composition comprising cross linked gelatin foam and sodium lauric sulfuric acid that has hemostatic effect.

C. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak in view of EP 5568 334 ('334).

The teachings of Pawelchak are discussed above.

Although Pawelchak teaches hemostatic agents incorporated into the gelatin foam product, however the reference does not specifically teach growth factor as claimed by claim 31.

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EP '334 teaches sponge comprising cross linked gelatin and active agent, preferably growth factors which enhances wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to provide hemostatic product comprising cross linked gelatin sponge, anionic surfactant and hemostatic agents as taught by Pawelchak, and add the growth factor taught EP '334 to the sponge. One would have been motivated to do so because EP '334 teaches that growth factors are preferred active ingredient to be added to hemostatic wound treating composition comprising gelatin because growth factors enhance wound healing and nerve regeneration. One would reasonably expected formulating composition comprising cross linked gelatin foam, anionic surfactant and growth factors wherein the composition successfully and effectively enhances wound healing and nerve regeneration.

(10) Response to Argument

- A.** APPELLANTS ARGUE THAT CLAIMS 22-25, 27-30, 32, 33, AND 42 ARE PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, UNDER 35 U.S.C. § 102(b).

Appellants argue that Pawelchak teaches a lyophilized foam sponge product formed from hydrocolloids, gelatin, pectin, and sodium carboxymethyl cellulose. The product is produced by forming an aqueous colloidal dispersion of hydrocolloids; aerating or foaming; freezing; and lyophilizing. Pawelchak teaches wetting

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agents/surfactants/dispersants are added to the colloidal dispersion prior to foaming and thus, if present at all, are dispersed uniformly throughout the material of the sponge. Then the uniformly dispersed mixture, is then poured into containers and frozen. At this point, the foam is an aqueous composition, not a preformed gelatin sponge, and is not cross-linked. Following lyophilization, "The lyophilized hydrocolloid foam product can be cross-linked."

In response to this argument, it is argued that it is argued that the reference clearly discloses method of making the foam by forming dispersion containing **aerated foamed gelatin**, which reads on preformed, and adding the surfactant to the dispersion read on **non-aqueous solvent** and wetting agent added to the gelatin composition, followed by drying of the dispersion and forming a sponge product (col.4, lines 40-47, 60-68; col.5, lines 1-2). Adding the surfactant to the dispersion containing foamed aerated gelatin as taught by the reference meet the limitation of coating the gelatin with the wetting agent by soaking as instantly claimed by claim 22 because appellants coated the gelatin foam by soaking the foam in the wetting agent. Further, **appellants themselves admit that the reference discloses crosslinking**. In any event, the present claims are directed to composition and all the elements of the composition are taught by the prior art. The limitation of "coating the gelatin sponge by soaking in" is directed to method of making the composition that does not impart patentability to composition claims. The present claims recite evaporating the solvent and this means the final product does not include the aqueous solvent. The present product is gelatin sponge and wetting agent substantially coated on the sponge as taught by the

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reference because the reference soaked the gelatin in the composition containing surfactant and the appellants coated their product by soaking gelatin in wetting agent (surfactant). The present claims are considered by “product by process claim”, and product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), wherein the product-by-process claim was rejected because the end product, in both the prior art and the claimed product were the same. The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Since the claimed product appears to be substantially identical to that of the prior art, the burden is shifted to appellant to show an unobvious difference between the claimed product and the prior art product and to come forward with evidence establishing an unobvious difference. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because

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of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974); *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983); *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). It has been held that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The reference process provided gelatin sponge coated with wetting agent as instantly claimed.

Further, the present claims' language does not exclude the step of freeze drying taught by the reference. The present specification disclosed drying.

Appellants argue that in the absence of the claimed structures having a coated surface, Pawelchak cannot disclose the performance of such structures to decrease hydration time resulting from the presence of such structures. The article of Pawelchak may optionally include a surface tension modifier to stabilize the foam prior to cross-linking. By contrast, an article of the pending claims has a cross-linked gelatin portion and a surface coating on the preformed cross-linked gelatin portion. Pawelchak does

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not disclose a wetting agent coating on at least a substantial portion of the surface of a preformed cross-linked gelatin sponge.

In response to this argument, applicants are reminded that the present claim is directed to a product. It is further argued that the mixture of gelatin and surface active agent (wetting agent) as disclosed by Pawelchak would inevitably leave some of wetting agent along with other ingredient on the surface of the article after drying. In light of the present claims' language "... **coated on at least a substantial portion** ...", the disclosure of the reference of forming a mixture meets the claims. The claims do not require coating, rather coating of substantial portion.

Appellants argue that Pawelchak discloses that the crosslinking agent may be added to the aerated or foamed colloidal dispersion which optionally may contain a surface tension modifier uniformly dispersed therein. The surface coating of the present invention imparts a novel structure to the coated foam sponge which produces a higher concentration of the wetting agent on the surface of the cross-linked foam sponge. The use of a non-aqueous solvent prevents irreversible damage to the foam which may result from contact with water.

In response to this argument, appellants are reminded by the scope of the present claims that is directed to a product, and all the elements of the product are disclosed by Pawelchak. Appellants admit that the reference discloses crosslinking agent and surface active agents added to the aerated gelatin foam. The surface active agent and crosslinking agent disclosed by Pawelchak is dispersed in the composition

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forming the foam. As such the after drying the composition, the dispersed surface active agent will inevitably present on the surface meeting the claimed limitation of “**coated on at least a substantial portion**”. Pawelchak does not teach the use of water.

Appellants argue that examples of Pawelchak lack surface tension modifier, as well as the lack of data related to hydration times. While some embodiments of Pawelchak may employ similar materials in producing hydratable sponges, the cited Tween 60 is only added to the precursor to a foam which may subsequently lyophilized and/or cross-linked.

In response to this argument, appellants’ attention is directed to **claim 25 of Pawelchak that recites crosslinking agent and claim 30 that recites surface active agents**. Claiming of crosslinking and surface active agent is evident of their being essential elements in preferred embodiments. Crosslinking agents are also disclosed in col.3, lines 36-39 and col.5, lines 18-20, and surface active agents are disclosed in col.4, lines 47-55. Regarding data related to hydration times, Pawelchak disclosed at col.3, lines 18-22 that “**the product of this invention is capable of absorbing and holding many times its weight of whole blood or body exudate**”. Hydration time of the sponge of the reference is inherent since the sponge has the same density as instantly claimed and contains the same ingredients in the same amounts.

While appellants admit that some embodiments use similar surface active agents, however argues steps of crosslinking is subsequent to adding the surface active agent. The examiner position is that the present claims are directed to a product, and

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this argument is directed to the process of making the sponge, as previously discussed in this examiner's answer.

Appellants argue that no preformed cross-linked sponge of Pawelchak is coated by exposing it to a non-aqueous solution of a wetting agent which is soluble in a non-aqueous solvent. There is no indication in the disclosure of Pawelchak that a post-applied surface coating is structurally equivalent to a material uniformly dispersed within a sponge and it would not be understood to be equivalent by one of ordinary skill in the art. The Examiner errs in asserting that the composition is anticipated because it contains similar components without properly taking into account that the materials of Pawelchak are not arranged as required by the claim.

In response to this argument, it is hereby repeated that the reference clearly discloses method of making the foam by forming dispersion containing **aerated foamed gelatin**, which reads on preformed, and **adding the surfactant** to the dispersion read on non-aqueous solvent and wetting agent added to the gelatin composition, followed by drying of the dispersion and forming a sponge product (col.4, lines 40-47, 60-68; col.5, lines 1-2). The reference disclosed **crosslinking** as admitted by appellants. Adding the surfactant to the dispersion containing foamed aerated gelatin meet the limitation of coating the gelatin with the wetting agent by soaking as instantly claimed by claim 22 because appellants coated the gelatin foam by soaking the foam in the wetting agent, as previously discussed in this examiner's answer. In any event, the present claims are directed to composition and all the elements of the composition are taught by

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the prior art. It is further argued that the mixture of gelatin and surface active agent (wetting agent) as disclosed by Pawelchak would inevitably leave some of wetting agent ingredient on the surface of the article. In light of the present claims' language "... **coated on at least a substantial portion...**", the disclosure of the reference of forming a mixture meets the claims.

Appellants illustrated in the experimental section of the pending application and noted in the paper of August 3, 2010, the wetting agent Tween 60, specifically cited in the disclosure of Pawelchak, causes premature foam collapse when incorporated directly into the foaming composition; however when coated onto the surface of a preformed sponge as taught by the pending application and claims, does not significantly collapse a preformed and cross-linked foam and provides the benefit of reducing hydration time from 6 minutes to 24-35 seconds.

In response to this argument, it is argued claim 22 is not directed to any specific surfactant. It is hereby repeated that the mixture of gelatin and surface active agent (wetting agent) as disclosed by Pawelchak would inevitably leave some of wetting agent ingredient on the surface of the article. In light of the present claims' language "**coated on at least a substantial portion ...**", the disclosure of the reference of forming a mixture meets the claims, as previously discussed. Regarding the hydration times, Pawelchak disclosed at col.3, lines 18-22 that "the product of this invention is capable of absorbing and holding many times its weight of whole blood or body exudate".

Hydration time of the sponge of the reference is inherent since the sponge contains the same density and same ingredients in the same amounts.

B. APPELLANTS ARGUE THAT CLAIM 26 IS PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, IN VIEW OF YASUSHI ET AL., JP 02- 182259, UNDER 35 U.S.C. § 103(a).

Appellants argue that all words in a claim must be considered in judging the patentability of that claim against the prior art. With regard to the rejections of claim 26 over Pawelchak in view of Yasushi et al. (JP 02-182259), the Advisory Action notes that "Yasushi is relied upon for the solely teaching of specific wetting agents as claimed by claim 26 and Song is relied upon for the solely teaching of inclusion of growth factor in wound dressing as claimed by claim 31". Accordingly, Yasushi does not overcome the deficiencies of Pawelchak as applied to independent claim 22 which does not include that limitation.

In response to this argument, it is argued that all the elements of the composition claimed by claim 22 are taught by Pawelchak, and Yasushi is relied upon for the solely teaching of specific wetting agents as claimed by claim 26. Yasushi teaches the equivalency between sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester as anionic surfactant added to the hemostatic gelatin sponge product. Song is relied upon for the solely teaching of inclusion of growth factor in wound dressing as claimed by claim 31. Song teaches that growth factors are preferred active ingredient to be added to hemostatic wound treating composition comprising gelatin because growth factors enhance wound healing and nerve regeneration.

Appellants argue that if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. Claim 26, which depends from nonobvious independent claim 22, also is believed to be nonobvious.

In response to this argument, it is argued that claim 22 is anticipated by the Pawelchak, as previously discussed. Claim 26 is obvious over the combination of Pawelchak in view of Yasushi and its rejection is proper under U.S.C. 103 (a).

C. APPALLANTS ARGUE THAT CLAIM 31 IS PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, IN VIEW OF SONG ET AL., EP 0 568 334, UNDER 35 U.S.C. § 103(a).

Appellants argue that the Advisory Action notes that "Yasushi is relied upon for the solely teaching of specific wetting agents as claimed by claim 26 and Song is relied upon for the solely teaching of inclusion of growth factor in wound dressing as claimed by claim 31". Accordingly, Song does not overcome the deficiencies of Pawelchak as applied to independent claim 22 which does not include that limitation. Claim 31, which depends from nonobvious independent claim 22, also is believed to be nonobvious.

In response to this argument, it is argued that all the elements of the composition claimed by claim 22 are taught by Pawelchak, and Song is relied upon for the solely teaching of inclusion of growth factor in wound dressing as claimed by claim 31. Song teaches that growth factors are preferred active ingredient to be added to hemostatic wound treating composition comprising gelatin because growth factors enhance wound healing and nerve regeneration. Claim 22 is anticipated by the Pawelchak. Claim 31 is

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obvious over the combination of Pawelchak in view of Song and its rejection is proper under U.S.C. 103 (a).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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